MAR 0 4 2013

ulrich medical USA

510(k) Summary

Date:	28 November 2012
Sponsor:	ulrich GmbH & Co. KG Buchbrunnenweg 12 89081 Ulm Germany Phone: +49 (0) 731-9654-1304 Fax: +49 (0) 731-9654-2802
Contact Person:	Hans Stover ulrich medical USA, Inc. 612 Trade Center Blvd. Chesterfield, MO 63005 (636) 519-0268 Office (636) 519-0271 Fax
Proposed Trade Name:	uCentum™ comprehensive posterior system
Device Classification	Class II and Class III
Classification Name:	Pedicle screw spinal system
Regulation:	888.3070
Device Product Code:	MNI, MNH, NKB
Submission Purpose:	This submission adds modified components (screw, rod and crosslink options).
Device Description:	The uCentum™ comprehensive posterior system consists of rods, polyaxial pedicle screws and crosslinks with locking set screws. The components are available in various sizes to accommodate differing patient anatomy. Rods are available straight and curved in a variety of lengths. Polyaxial screws are available in a variety of diameter-length combinations. Crosslinks are offered in five lengths. The system can be implanted in open or minimally invasive procedures.
Intended Use:	The uCentum™ comprehensive posterior system is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion of the thoracic, lumbar and sacral spine (T1-S2). When used as a posterior spine thoracic/lumbar system, the uCentum is intended for the following indications: degenerative disc disease (as defined by back pain of discogenic with degeneration of the disc confirmed by patient history and radiographic studies), spinal stenosis, spondylolisthesis, spinal deformities (i.e., degenerative scoliosis, kyphosis, and/or lordosis), fracture, spinal tumor, pseudarthrosis and failed previous fusion.

Materials: The uCentum™ system components are manufactured from titanium alloy (Ti-6Al-4V ELI) as described by ASTM F136.

Predicate Devices: tangoRS™ (K052385 and K120891)
flamenco™ (K102853)
Moss Miami (K992168/K022623)
Revlock™ Fenestrated Screw System (K110280)

Performance Data: Mechanical testing of the worst case uCentum™ constructs included static and dynamic compression bending, and static torsion according to ASTM F1717.
The mechanical test results demonstrated that uCentum™ performance is substantially equivalent to the predicate devices.

Technological Characteristics: The uCentum™ comprehensive posterior system possesses the same technological characteristics as one or more of the predicate devices. These include:

- performance (as described above),
- basic design (rod-based, having screw anchors),
- material (titanium alloy) and
- sizes (dimensions are comparable to those offered by the predicate systems).

Therefore the fundamental scientific technology of the uCentum™ comprehensive posterior system is the same as previously cleared devices.

Conclusion: The uCentum™ comprehensive posterior system possesses the same intended use and technological characteristics as the predicate devices. Therefore the uCentum™ comprehensive posterior system is substantially equivalent for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 4, 2013

ulrich GmbH & Company KG
% ulrich medical USA, Incorporated
Mr. Hans Stover
612 Trade Center Boulevard
Chesterfield, Missouri 63005

Re: K123717
Trade/Device Name: uCentum™ comprehensive posterior system
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNH, MNI
Dated: November 28, 2012
Received: December 4, 2012

Dear Mr. Stover:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Precautions/Warnings/Contraindications section of the device's labeling:

"The safety and effectiveness of this device has not been established when used in conjunction with bone cement or for use in patients with poor bone quality (e.g., osteoporosis, osteopenia). This device is intended only to be used with saline or radiopaque dye."

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Christy L. Foreman

Christy Foreman
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K123717

Device Name: **uCentum™ comprehensive posterior system**

Indications for Use:

The uCentum™ comprehensive posterior system is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion of the thoracic, lumbar and sacral spine (T1-S2). When used as a posterior spine thoracic/lumbar system, the uCentum is intended for the following indications: degenerative disc disease (as defined by back pain of discogenic with degeneration of the disc confirmed by patient history and radiographic studies), spinal stenosis, spondylolisthesis, spinal deformities (i.e., degenerative scoliosis, kyphosis, and/or lordosis), fracture, spinal tumor, pseudarthrosis and failed previous fusion.

Prescription Use __X__ AND/OR Over-the-Counter Use_____

(21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ronald P. Jean -S

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K123717